COMMUNITY HIV/AIDS CHAMP MOBILIZATION PROJECT
HHS WATCH

June 2006 -

PEMS Takes a Break

The CDC has indefinitely put off implementing its oft-delayed Program Evaluation and Monitoring System (PEMS). PEMS is a complicated computerized system that CDC has created to track local agencies' use of federal HIV prevention funds. Further, it collects data on clients' HIV risk status and whether their behavior changed after attending counseling or other prevention programs. The program has created considerable protest, especially due to the invasive way it inserts itself into client-staff interactions. There are considerable concerns about invasions of privacy, alienation of clients, program impact and the cost that PEMS incurs for agencies struggling with shrinking funding available for prevention (see *HHSWatch*, December, 2005 and March, 2006).

Agencies receiving CDC prevention funding were supposed to start collecting client data for counseling and testing in January, then in April, and finally October. A May 31 letter from the current acting director of the Divisions of HIV/AIDS Prevention (DHAP), Timothy Mastro, now tells agencies that they can forget about the October date, too. The latest postponement grew out of a meeting between the CDC and funded agencies that took place on April 25-26. During the meeting, PEMS received heavy criticism from local health departments and community organizations, who also complained of lack of preparedness.

Mastro conceded, "PEMS is like a plane that's too heavy and can't take off – we're looking to lighten the load. We want something that will be simpler, can be implemented, and will give us useful data."

The CDC has reorganized the PEMS development team, bringing it under Mastro's direct control. The Centers will also organize a PEMS Users Group to critique the overall system as well as a "PEMS Variables Group" to reduce the data collection burden. In the course of the discussions at the stakeholders meeting and other consultations, it became clear that there is no central set of evaluation questions nor an analysis plan explaining how CDC plans to use PEMS data. Establishment of this set and plan have now become one of the agency's priorities to pull together as a step towards reducing, and justifying, data collection requirements.

It seems certain that PEMS will survive in some form. The CDC is already requiring collection of "agency-level" aggregate data that tracks how agencies are spending their prevention grants. As for changes in the personal data requirements, Sean Barry, CHAMP's Director of Prevention Policy, stresses that a lot of work remains. He says, "The fixes we really want will cost time and money. The CDC will do some, but *they* don't really want to. There continue to be major disagreements over data collection and protecting client privacy. The CDC emphasizes collaborative solutions, but the people that access HIV services haven't been part of discussion."

A Vaccine for Girls Only – What about Boys, Women?

The FDA officially approved Merck & Co.'s version of the HPV vaccine ("Gardasil") on June 8. The vaccine has proved effective against four strains of the sexually transmitted human papillomavirus (HPV). Among these are HPV 16 and 18, responsible for about 70% of female cervical cancers and precancerous abnormalities. HPV 16 and 18

are also the triggers for many vaginal, vulval and anal malignancies. The other two strains, HPV 6 and 11, cause 90% of genital warts as well as a large number of vaginal and cervical tract cell abnormalities.

The FDA approval is highly limited: It only covers girls and young women. The vaccine, the first ever for an STD, is being treated instead as the first ever anti-cancer vaccine – which is true, but much more is involved.

Overall, the virus is estimated to cause 25,000 malignancies per year in women and 10,000 in men. HPV 16- and 18-induced anal cancer affects gay men and other men who have sex with men, as well as women. HPV can also be a source of penile cancer. Then there are the genital warts, which affect over 1 million men and women a year in the US. Warts from HPV also sometimes appear on the larynx, where they obstruct breathing.

Finally, there is the question of "herd immunity" – immunizing men ultimately protects women, too. Even young women will not get the full theoretical protection because their male sexual partners will not be immunized.

The question of vaccinating "older" women, i.e. those older than 26, also merits a second look. While some studies have found the highest rates of HPV infection in younger women just beginning sexual activity, there is no doubt that every age group has a substantial rate of HPV acquisition. (Fortunately, the rate of HPV clearance does not seem to increase with age.)

It is true that the efficacy data Merck submitted to the FDA came from trials conducted only in young females. Those trials showed close to 100% prevention of cervical abnormalities and warts. Merck did present trial results from 9 to 15 year-old boys, but the results showed only that boys had a substantial immune response, not that the vaccine is protective in men. There also was no data on protection against anal cancer or in older women. All these aspects are the subject of ongoing trials, but it would not be difficult to make a leap from the current data and approve the vaccine for boys and older women. Until the FDA reconsiders its position, there will be a huge gap in the vaccine's coverage.

Of course, any one outside the officially approved population could seek the vaccination on their own. Beyond the need to make themselves a special case at the doctor's office, Gardasil's high price – $360 for the full three-shot course – will prove a major deterrent. Insurance companies and government programs will not pay for unapproved vaccinations.

There is also considerable political pressure surrounding this vaccine. Abstinence-until-marriage advocates frequently exaggerate the threat posed by HPV to support their position. On June 29, the CDC's Advisory Committee on Immunization Practice unanimously voted to recommend HPV vaccination for all 11-12 year old girls (though the committee allowed that the vaccine could be given as early as 9 years of age and as late as 26). ACIP guidelines pave the way for funding by the US Vaccine for Children program. They also encourage states to require vaccination for students.

And here's where the political fireworks will start. At last February's ACIP meeting Moira Gaul, a policy analyst at the Family Research Council, strongly opposed mandatory vaccination, saying it should be the parents' decision. Gaul laid out her organization's arguments for not relying on vaccination to prevent HPV. She noted that the vaccine will not prevent other STDs or even other strains of HPV. STD prevention, she said, should follow a risk elimination strategy similar to that used to reduce tobacco, drug and alcohol use. That would mean depicting single, lifelong monogamous relationships as the best way to avoid the physical and psychological damage wrought by STDs.

The Ever Strengthening Case for Condom Protection

HPV: Just as the HPV vaccine approval came out, the *New England Journal of Medicine* published a major study showing that condoms offer women significant protection against the virus. First reported in *HHSWatch* a year ago, this study took place in 82 female college students who had not had previous heterosexual vaginal intercourse. The women kept diaries of their sexual activity and condom use. The overall rate of HPV acquisition in the 12 months following first intercourse was 38%. Use of condoms during all acts of vaginal intercourse reduced the risk of acquiring HPV by 60% compared to using condoms on few or no occasions. Having only one sex partner or only sex partners with no prior sexual experience were other highly protective factors. For HPV-induced cervical abnormalities, 100% condom use proved 100% protective.

Genital herpes: Last November, a University of Washington group reported on a second study they did on the protective effect of condoms on genital herpes (HSV-2, or herpes simplex virus-2). The study complements a 2001 report from the same researchers showing that condom use dramatically reduced herpes in women in whose male sexual partner had herpes. You need a very large study to evaluate herpes protection in men because the male-to-female transmission rate is much lower than in the reverse direction. The current study recruited high-risk participants at STD clinics. Almost 1,400 of the 1,850 participants were men, including an unspecified number of men who have sex with men. Data for both studies were collected in parallel during the late 90s, although the published reports are four years apart.

The current study found that condoms also protect men from HSV-2. Risk of herpes was about half as great in men who used condoms for more than 75% of sexual intercourse compared with men who used condoms 0% to 25% of the time. The protective effect was somewhat less for women and was not considered statistically significant given the smaller number of female participants. The study also found that number of sex partners or number of new sex partners did not significantly increase HSV-2 risk.

It may be that the women in this study had less risk than the men for various undetermined reasons. *Generally, studies underestimate the protection offered by condoms because those with little disease exposure tend to use condoms more rarely.*

If none of your sex partners have an STD, then you won't become infected with or without a condom. If all your sex partners have that STD, then you could well become infected the few times you don't use condoms. There is also the question of whether study participants use condoms properly, which is rarely investigated. Also, people who contract the STD under study may over-report their frequency of condom use.

Chlamydia and gonorrhea: Condoms seem to be an ideal means for risk reduction in HIV, chlamydia and gonorrhea because they are all transmitted through genital fluids. Researchers consistently report that condoms confer very high levels of protection against HIV. In contrast, chlamydia and gonorrhea studies are all over the map. The underlying issue is that HIV transmission is comparatively rare whereas about half of exposures to chlamydia or gonorrhea result in infection. These latter two diseases are also far more prevalent in the total US population. Inconsistent or improper condom use is hard to detect in studies and yet is far more likely to result in disease transmission than it is with HIV.

This winter, Lee Warner and others from the CDC published a review of 45 heterosexual studies looking at the correlation between condom use and acquiring chlamydia or gonorrhea. Among all the factors affecting

condom's influence, they examined whether the studies adjusted for consistent and correct use, the temporal pattern of infection (which came first: condom-using habits or the STD?), and the amount of sex with infected partners. The authors did not critique the accuracy with which studies made such adjustments. Thirty-five of the 45 studies considered one or none of these four confounding factors, and only 15 (43%) reported a statistically significant protective effect for condoms. Of the 10 studies that took 2 or 3 of these factors into account, 8 (80%) found a statistically significant risk reduction. This "meta-result" was itself statistically significant.

The right to self-defense: In 2001, an HHS-sponsored committee issued a report saying that condoms clearly protected against pregnancy, HIV and female-to-male gonorrhea transmission, but that the data were sparse and inconclusive for other STDs. That report appeared in the aftermath of a Congressional bill demanding that the FDA examine whether condoms labels needed to include warnings about lack of protection against STDs, HPV in particular. Five years later and under heavy pressure from Sen. Tom Coburn (R-OK), Rep. Mark Souder (R-IN) and other pro-abstinence members of Congress, the FDA issued draft new labeling regulations that downplay the protection condoms provide, especially for herpes and HPV (see *HHSWatch,* November 2005). Already on shaky grounds, the draft was surpassed by the scientific evidence immediately after it was issued.

The evidence for protection beyond HIV is becoming more and more incontrovertible, to the extent that determined opponents of condoms are beginning to recognize the moral quandary that opposition puts them in. In April the retired Catholic archbishop of Milan, Cardinal Carlo Martini, told L'Espresso magazine that condoms could be regarded as the lesser evil: "A spouse with AIDS has to protect the other partner, for whom self-protection is also a duty. The question is whether the religious authorities can advocate such means of defense, seeming to put the other morally defensible methods, including abstinence, in second place." Indeed, if you admit that condoms are effective, it becomes very tricky to decide where the right to self-defense ends.

This HHS Watch was written by David Gilden

HHSWatch, a watchdog newsletter from CHAMP, monitors and reports on activities related to HIV prevention at Health and Human Services agencies, including CDC, NIH, HRSA and SAMHSA.

HHSWatch is a resource for community members, policy advocates, researchers and anyone interested in more fully understanding and tracking the committees, panels and administrators whose recommendations and decisions affect our work.

HHSWatch is committed to providing an outlet for those concerned about infringements upon science-based HIV prevention and treatment, and will respect your wishes for confidentiality. If you are interested in contributing information or suggesting a story, please contact champ@champnetwork.org.

COMMUNITY HIV/AIDS MOBILIZATION PROJECT (CHAMP)
594 Broadway, Suite 700 New York, NY 10012
tel. (212) 937-7955 x 10
www.champnetwork.org